

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 14, 2008 has been entered.

Claims 1-9 are pending. Claim 7 is withdrawn. Claims 1-6, 8, and 9 are examined on the merits to the extent they read on the elected subject matter.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8, and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the recitation that "the at least one oxidized starch and the at least one cellulose compound are chemically bonded to one another" is considered new matter. The Chiodero declaration under 37 C.F.R. 1.132 filed January 14, 2008 asserts that under the conditions described in Example 1 of the disclosure, oxidized starch and hydroxylpropylmethyl

cellulose are chemically bonded to one another. However, there is no demonstration that the disclosure teaches that any of the other celluloses listed in the claim (hydroxypropyl cellulose, hydroxyethyl cellulose, carboxymethyl cellulose) are also chemically bonded to the at least one oxidized starch. Because the specification as filed fails to provide clear support for the new claim language, a new matter rejection is clearly proper.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite by the recitation "the oxidized starch" at line 2 since it lacks antecedent basis. It is suggested that it be replaced with "the at least one oxidized starch." Claim 1 is also rendered indefinite by the recitation "the at least one substance" at lines 9 and 10 since it lacks antecedent basis. It is suggested that it be replaced with "the at least one active substance." Claims 1-6, 8, and 9 are thus rejected under 35 U.S.C. 112, second paragraph.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. (US 6,419,903) in view of Ushimaru et al. (US 5,368,861).

Xu et al. discloses a “rapidly dissolvable orally consumable film composition” comprising “water soluble, low viscosity hydroxyalkylmethyl cellulose and water dispersible starch and a flavoring agent” (abstract).

Xu et al. teaches that the cellulose is present in the film composition in an amount ranging from about 10 to about 60% by weight (column 3, lines 8-11), which meets the cellulose weight requirements recited in instant claim 1. Further still, Xu et al. teaches that the hydroxyalkylmethyl cellulose may be hydroxypropyl methyl cellulose (claim 2), thus meeting limitations in instant claims 1 and 4.

The pregelatinized starch in the film composition is present in an amount ranging from about 5 to about 50% by weight (column 3, lines 47-49), which fits within the weight range recited in instant claim 1.

The flavoring agent can be considered a cosmetic, aromatic, pharmaceutical and/or food substance. Moreover, this flavoring agent is present in the film composition in an amount ranging “from about 2.0 to about 10% by weight” (column 4, lines 3-6). Given that “about 10%” embodies percentages above 10%, such as 10.1%, the Xu invention clearly anticipates instant claim 1 which requires an active substance in an amount of from 10 to 50% by weight relative to the total weight of the film composition. Moreover, the composition can further comprise active breath freshening agents (column 4, line 40-42) which may be present in the composition at a concentration of about 0.1 to about 2.0% by weight (column 4, lines 46-49). These breath freshening agents can be considered additional active substances, thus contributing to the amount of active substances present in the film composition. Even if the flavoring agent were present in amount of 10% by weight of the composition, the presence of the breath freshening agents result in a composition comprising active substances in a concentration of more than 10% by weight of the composition.

Xu et al. also teaches that the film composition quickly dissolves in the mouth and “...generally in less than 30-40 seconds” (column 2, lines 57-58). Thus, the film composition can dissolve at lengths of time shorter than 30-40 seconds, including 10 seconds and 7 seconds. Moreover, lengths of time shorter than 30-40 seconds can be considered a dissolution time of “a few seconds.” Thus, the Xu invention meets the dissolving time limitations recited in instant claims 1, 8, and 9.

Finally, in the preparation of the Xu invention, the starch forms a homogeneous mixture with cellulose (column 4, lines 54-63). A slurry emulsion is formed with the additional

ingredients, and this emulsion was cast on paper at 25°C and dried at 110°C to form a solid thin film (column 5, lines 1-3).

Xu et al. differs from the claimed invention in that it does not disclose that the starch in the film composition is oxidized starch, nor does it expressly disclose that the starch present in the composition is chemically bonded to the cellulose compound present.

Ushimaru et al. discloses a gastric preparation for rapid release of a drug comprising a substance capable of producing a gel in water selected from the group consisting of carboxymethyl cellulose, hydroxypropyl cellulose, hydroxyethyl cellulose, and oxidized starch (claim 1).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have substituted the pre-gelatinized starch in the Xu film composition with oxidized starch to achieve the predictable result of creating an orally consumable film composition. The substitution of one known form of water dispersible starch for another form would have been obvious, and the person of ordinary skill has good reason to pursue the known options within his or her technical grasp. Moreover, given that an oxidized starch and hydroxypropylmethyl cellulose are combined in an emulsion and dried at 110°C, it would seem that a chemical bond would have formed if it was also formed by the applicant's experiment, as discussed in the Chiodero declaration. Thus, the claimed invention is rendered obvious.

Claims 1-6, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. and Ushimaru et al. as applied to claims 1, 4, 8, and 9 above, and further in view of Hata (US 4,345,032) and Sharik (US 5,206,026).

As discussed above, Xu et al. and Ushimaru et al. render claims 1, 4, 8, and 9 obvious. However, these references do not expressly disclose that bacteria is present in the disclosed composition.

Hata discloses that specific lactobacillus strains have the ability to deodorize foul breath (column 1, lines 42-45).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have substituted the flavoring agent of the Xu invention with specific lactobacillus strains appropriate for deodorizing foul breath. One of ordinary skill in the art would have been motivated to do this since these lactobacillus strains would have served as breath freshening agents, as required by the Xu invention.

Xu et al. also differs from the instant invention in that it does not teach a composition comprising hydroxyethyl cellulose or hydroxypropyl cellulose.

Sharik discloses an instantaneous delivery film for the delivery of a therapeutic agent (abstract), wherein the delivery film comprises of a film-forming polymer which must be water soluble (column 3, lines 15-27). Suitable film-forming polymers include hydroxyethyl cellulose and hydroxypropyl cellulose.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have modified the Xu invention such that hydroxyethyl cellulose or hydroxypropyl cellulose is used as the cellulose of the Xu invention. One of ordinary skill in the art would have been motivated to do this since these celluloses would have enabled the formation of a film. Thus, a holding of obviousness is clearly required.

***Response to Arguments***

Applicant's arguments filed January 14, 2008 have been fully considered but they are not persuasive. As noted above, the Chiodero declaration filed January 14, 2008 provides no demonstration that the disclosure teaches that any of the other celluloses listed in the claim (hydroxypropyl cellulose, hydroxyethyl cellulose, carboxymethyl cellulose) besides the cellulose described in Example 1 of the disclosure are also chemically bonded to the at least one oxidized starch. Moreover, given that a Xu film composition comprising oxidized starch in place of pre-gelatinized starch is rendered obvious, it would appear that the same chemical bonding described in the Chiodero declaration would have also occurred in the Xu film composition comprising oxidized starch.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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